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The importance of an initial sober month of in the treatment of alcohol dependence with a focus on controlled drinking: short- and long-term effects on alcohol consumption and health status

Submission date
13/11/2024

Recruitment status
No longer recruiting

Registration date
22/11/2024

Overall study status
Ongoing

Last Edited
21/01/2026

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
This study aims to find out if taking a break from drinking alcohol for a month before starting treatment for controlled drinking leads to better health outcomes. While controlled drinking is effective for people with mild to moderate alcohol dependence, those with severe dependence are usually advised to stop drinking completely. A "dry month" has been shown to improve heart, metabolic, and mental health in moderate drinkers, but its effects on people with alcohol dependence are not well known. This study will compare the health and drinking habits of people who take a month off alcohol before treatment to those who do not.

Who can participate?
Adults seeking treatment for alcohol use disorder, who aim to control their drinking, and do not have major psychiatric conditions can participate in this study.

What does the study involve?
Participants will be randomly assigned to one of two groups. One group will receive Cognitive and Behavioral Therapy (CBT) for controlled drinking, including a 30-day period of complete abstinence at the start. The other group will receive the same CBT treatment without the initial abstinence period. Both groups will have five therapy sessions over four months and can choose to receive medication support if desired. Health and drinking habits will be measured at the start, after one month, and after six months.

What are the possible benefits and risks of participating?
Participants may benefit from improved health and better control over their drinking. The study will help determine if a period of abstinence before treatment leads to better outcomes. Risks may include the challenges of abstaining from alcohol and the time commitment required for therapy sessions and assessments.

Where is the study run from?
The study is conducted at the Alcohol and Health Clinic, Riddargatan 1 in Stockholm, Sweden.

When is the study starting and how long is it expected to run for?
October 2020 to December 2027

Who is funding the study?
The study is funded by the Stockholm City Council (ALF Medicin) and the Research Council of the Swedish Alcohol Retailing Monopoly.

Who is the main contact?
Sven Andréasson, PhD, sven.andreasson@ki.se

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
2021-01959

Study information

Scientific Title
The importance of an initial month of complete sobriety in the treatment of alcohol use disorder with a focus on controlled drinking: effects on alcohol consumption and health status in short- and long-term follow-up

Study objectives
This project hypothesizes that a one-month period of complete sobriety before treatment focused on controlled drinking will lead to better treatment outcomes in both the short and long term, compared to treatment without prior sobriety. Treatment including prior sobriety is

expected to reduce alcohol consumption, alcohol cravings,, and reduce severity of the alcohol use disorder. Additionally, it is anticipated that cardiovascular, metabolic, and mental health will improve both in the short term (1 month) and in the longer term (6 months).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 31/05/2021, Etikprövningsmyndigheten (Swedish Ethical Review Authority) (Box 2110, Uppsala, 750 02, Sweden; +46 10-475 08 00; registrator@etikprovning.se), ref: 2021-01959

Primary study design
Interventional

Study design
Single-centre randomized controlled trial

Study type(s)
Efficacy, Treatment

Health condition(s) or problem(s) studied
Alocohol use disorder

Interventions
Cognitive behavioral treatment for the goal of controlled drinking with an add-on of a sober month including optional pharmacological support compared to cognitive behavioral treatment for the goal of controlled drinking only (treatment as usual).

Participants with a treatment goal of controlled drinking were randomised to either begin their treatment with a one month sobriety period before starting CBT treatment or to one month of trying to reduce their drinking without sobriety.

Following this first month, both groups received the same treatment program. This was a 12 week CBT program with with four treatment sessions and homework assignments. Patients requesting pharmaceutical treatment were given prescriptions for naltrexone or acamprosate.

At 4 weeks there was a follow-up with biochemical markers and questionnaires, and at 24 weeks a concluding follow-up was conducted with biochemical markers and questionnaires. Following this, treatment, as well as research participation, was terminated.

Randomisation was performed using an online tool with randomisation in blocks of 10 using a web-based randomisation service.

Intervention Type
Behavioural

Primary outcome(s)
1. Mean weekly alcohol consumption (in standard drinks) is measured using a structured interview following the Timeline Follow-Back (TLFB) method at baseline and 6-month follow-up

2. Frequency of binge drinking (4 or more/5 or more, women/men, standard drinks per drinking occasion) in the previous 30-day period is measured using a structured interview following the Timeline Follow-Back (TLFB) method at baseline and 6-month follow-up

Key secondary outcome(s)
1. Alcohol consumption is measured using Phosphatidylethanol (PEth) at one and six months post inclusion
2. Liver function is measured using analyses of Gamma-glutamyltransferase (GGT), aspartate aminotransferase (AST), and alanine aminotransferase (ALT) at one and six months post inclusion
3. Goal-setting (abstinence or reduced consumption) is measured using a goal-setting questionnaire at one and six months post inclusion
4. Degree of alcohol dependence is measured using a questionnaire for dependence criteria according to ICD-10 and DSM-5 at one and six months post inclusion
5. Degree of alcohol dependence is measured using the Alcohol Use Disorders Identification Test (AUDIT) at one and six months post inclusion
6. Motivation for change and confidence in the ability to change drinking habits is measured using self-assessment on a Visual Analog Scale (VAS) at one and six months post inclusion
7. Heart rate is measured at one and six months post inclusion
8. Blood pressure is measured using an automatic blood pressure monitor after 10 minutes of rest at one and six months post inclusion
9. Lipids (HDL and LDL cholesterol, and triglycerides) are measured using blood samples at one and six months post inclusion
10. Glucose is measured using blood samples at one and six months post inclusion
11. Level of anxiety is measured using GAD-7 at one and six months post inclusion
12. Level of depression is measured using PHQ-9 at one and six months post inclusion

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Fulfilment of an alcohol use disorder/Alcohol dependence diagnosis, defined as meeting 2 or more criteria for alcohol use disorder according to the DSM-5, or 3 or more criteria according to ICD-10
2. Alcohol consumption exceeding 10 standard drinks (12 grams of pure ethanol) and/or binge drinking exceeding 4/5 standard drinks (women/men) per occasion, one or more times per month in the 30 days before the assessment day
3. A stated treatment goal of controlled drinking
4. Sufficient skills in reading and writing in Swedish

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit

18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Initiated a sober period/abstinence goal before inclusion
2. A severe psychiatric or somatic comorbidity, e.g., psychosis, bipolar disorder, liver disease with transaminase levels exceeding three times clinical cutoffs, ongoing treatment for a severe cardiovascular disease, and cancer

Date of first enrolment
01/01/2023

Date of final enrolment
31/01/2025

Locations

Countries of recruitment
Sweden

Study participating centre
Mottagningen för alkohol och hälsa
Riddargatan 1
Stockholm
Sweden
11435

Sponsor information

Organisation
Karolinska Institutet

ROR
https://ror.org/056d84691

Funder(s)

Funder type
Industry

Funder Name
ALF Medicin

Funder Name
Forskningsrådet om Hälsa, Arbetsliv och Välfärd

Alternative Name(s)
Swedish Research Council for Health, Working Life and Welfare, Forskningsrådet om Hälsa, Arbetsliv och Välfärd, FORTE

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be considered to be available upon request by the principal investigator: Sven Andreasson, sven.andreasson@ki.se

IPD sharing plan summary
Available on request, Stored in non-publicly available repository